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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/611,780	07/07/2000	Erik Marcussen	5766.200-US	7010

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EXAMINER

HENDRICKS, KEITH D

ART UNIT	PAPER NUMBER
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1761

DATE MAILED: 11/29/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/611,780

Applicant(s)

MARCUSSEN ET AL.

Examiner

Keith Hendricks

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 16 February 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,4-16 and 33-43 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,4-16 and 33-43 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date: _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on February 16, 2005, has been entered.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

i. Claims 1, 4-16 and 33-43 (all pending) are rejected under 35 U.S.C. 102(b) as being anticipated by Herrman et al. (WO 97/43482).

As previously presented on the record:

Herrman et al. disclose the production of an enzyme granulate made by a mixer granulation process. The process comprises adding to an enzyme preparation, a cereal grain or legume flour, such as wheat, rye, soy, pea, etc., which has been treated by dry superheated steam, and ground. The enzymes listed at pages 10-11 include oxidoreductases, hydrolases, etc. As shown in claim 1 of the reference, the process "is characterized by the fact that one first prepares a wet granulate" which comprises the enzyme mixture, and "75 to 99 parts by weight (including moisture content) of an organic flour with a degree of grinding of 30 to 100%", as well as optional granulation and/or formulation agents, wherein subsequently the wet granulate "is further dried", and optionally coated. A high-shear mixing apparatus is utilized to form the granule. As shown in claim 22, the finished product, which has been dried, comprises the dried enzyme mixture, and "96.92 to 43.8 wt. % (dry substance)" of the flour substance. Further, at page 13 of the reference, "granulation and formulation auxiliary agents" are listed, which "can be added in an amount

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up to [a] maximum of 20%" of the prepared moist granule. These agents include inorganic compounds such as silicates, kaolin, bentonite, alkali chlorides and alkali sulphates, and calcium carbonate and calcium sulphate. Whether specifically named as the intended particulate or not, these compounds would thus meet the limitations of instant claims 4-7 and 13, and constitute less than 75% by weight of the finished granule, and their mean size would be commonly available in particles of a "mean size of more than 40 μm ."

Common particle size ranges and percentage distributions within flours were well-known and documented throughout the art, and such flours were known to have "a mean size of more than 40 μm " (instant claim 1). For example, common particle sizes of pasta wheat flours, which are even smaller than traditional wheat flours, are in the 550-150 micrometer granulation particle size range; some having a more standardized flour with a granule range of 350-130 micrometers (*Handbook of Cereal Science and Technology*, Lorenz et al., 1991, page 16), and corn (maize) was known to be in "the commonly used particle-size range (100-1,000 μm)" (*Influence of Particle Size on the Twin-Screw Extrusion of Corn Meal*, B. W. Garber, et al., Cereal Chem. 74(5):656-661, Copyright 1997 by the American Association of Cereal Chemists, Inc.).

It is noted that in the most recent amendment, instant claim 1 has been amended to recite that the particulate component has a "mean size of more than 100 μm in the longest dimension", and new claims 42 and 43 recite that said particulate component has a "mean size of more than 140 μm " and 200 μm , respectively, "in the longest dimension."

Applicant's arguments filed February 16, 2005 and prior, have been fully considered but they are not persuasive. Throughout prosecution, applicant has argued that the Herrman et al. reference does not teach (a) adding *less than 75* of 100 parts by weight of a particulate component, (b) adding *more than 25* of 100 parts by weight of an enzyme or an enzyme and granulating agent, and/or most recently, that (c) the mean size of the particulate component of the reference granule is not more than 100 μm in the longest dimension. These arguments have been considered, and have not been deemed persuasive. For the sake of consolidating the prosecution history, the Office will respond to each of these arguments herein.

Regarding (a) the addition of "less than 75 of 100 parts by weight of a particulate component", it is noted that the reference specifically teaches that "75 to 99 parts by weight (*including moisture content*) of an organic flour" (emphasis added), being the particulate component, is added to the enzyme component. After drying, this results in an enzyme-containing granule with "96.92 to 43.8 wt. % (dry substance)" of the flour substance. As applicant has pointed out in previous responses regarding the enzyme component, the dry weight is that which is measured, and thus if the organic flour component is present at 75% *with*

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moisture, as specifically stated by the reference, then it must be present at *less than 75%* without the moisture, i.e. by dry weight.

Regarding (b) the addition of "*more than 25 of 100 parts by weight of an enzyme or an enzyme and granulating agent*," this was addressed in the Advisory Action of August 20, 2004. Therein, it was stated that applicant's arguments at page 7 of the response referred to the "enzyme" alone, and dismissed the teachings of the reference due to the liquid component of the enzyme preparation used by Herrman et al. It is important to note that applicant's claims recite the use of either (a) an enzyme, *or* (b) "an enzyme and granulating agent". Reference to page 14 of applicant's own specification states that *liquid* granulating agents are useable within the claimed invention, and lines 24-25 specifically state that water is such a liquid granulating agent. The amount of enzyme and granulating agent (i.e. liquid) utilized by the reference examples would provide an amount within the instant claims. Still further, at page 13 of the reference, "granulation and formulation auxiliary agents" are listed, which "can be added in an amount up to [a] maximum of 20%" of the prepared moist granule. Therefore, the enzyme and granulating agent combined clearly exceed that of 25% of the granule.

Regarding argument (c) as stated above, i.e. that the mean size of the particulate component of the reference granule is not more than 100 μm in the longest dimension, this has also been previously addressed on the record, notably from the first Office action. As previously established, common particle size ranges and percentage distributions within flours were well-known and documented throughout the art, and such flours were known to have a mean size of more than 40 μm , and in fact, more than 100 μm or even 200 μm . For example, common particle sizes of pasta wheat flours, which are even smaller than traditional wheat flours, are in the 550-150 micrometer granulation particle size range; some having a more standardized flour with a granule range of 350-130 micrometers (*Handbook of Cereal Science and Technology*, Lorenz et al., 1991, page 16), and corn (maize) was known to be in "the commonly used particle-size range (100-1,000 μm)" (*Influence of Particle Size on the Twin-Screw Extrusion of Corn Meal*, B. W. Garber, et al., Cereal Chem. 74(5):656-661, Copyright 1997 by the American Association of Cereal Chemists, Inc.). As flours were known in the art to have mean particle sizes above 100 μm and more, this meets the instant claim limitations, and applicant's arguments are not deemed persuasive.

ii. Claims 1, 4-16 and 33-43 (all pending) are rejected under 35 U.S.C. 102(e) as being anticipated by De Lima et al. (US PAT 6,136,772).

De Lima et al. disclose enzyme-containing granules and processes for their production. Lines 22-25 of column 5 state that the cores of the granules (i.e., corresponding to the "particulate component" of the instantly-claimed invention) may comprise "a total of at least 25% w/w (based on total core weight), such as at least 50% w/w, of starch and/or modified starch." Column 10 addresses the issue of "the mean particle size of the granules (and in many cases, correspondingly, of the core particles therein)." "The optimal core particle size will generally depend on the intended use of the final enzyme-containing granule." "By way of example, for detergent applications the preferred mean granule particle size (and, in many cases, the corresponding mean core particle size) will often be in the range of 250-2000 μm (such as 300-2000 μm)." Further at column 10, it is stated that "granular core particles suitable as the basis for enzyme-containing granules in accordance with the present invention may be prepared, e.g., by conventional granulation methods such as tumbling, rolling, pelletization, extrusion/-spheroidization, and/or mechanical agitation of the starting material, e.g. starting material comprising starch or a silicate/siliceous material."

The amount of enzyme is addressed at column 15, lines 59-62: "the content of enzyme (calculated as pure enzyme protein) in a granule of the invention will typically be in the range of from about 0.5% to 20% by weight of the enzyme-containing granule." Regarding the amount actually added during the process, this also falls within this range, as can be seen from the teachings at columns 13-14 of the reference. "In the process of the invention it is preferable that the enzyme-containing liquid medium (solution or solution/-dispersion) is added to the particulate cores in a weight ratio (liquid medium:cores) of at least 0.05:1, more preferably at least 0.1:1, such as at least 0.15:1, for example at least 0.2:1, and often at least 0.5:1." Column 13 states that

When an aqueous, enzyme-containing solution/dispersion is employed in accordance with the invention, the solution (i.e. the liquid phase of the aqueous medium) will normally preferably have a dry matter content of from 2% w/w to 50% w/w [dry matter consisting of enzyme protein(s), possibly together with other organic and inorganic materials]. When dispersed enzyme is present, the solution/dispersion will suitably have a dry matter content of from 10% w/w to 70% w/w [including dry matter originating from both dissolved and dispersed (undissolved) material].

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Therefore, the teachings of the reference encompass the utilization of a 70% w/w dispersed enzyme solution, at a weight ratio of "at least 0.5:1" in relation to the core particulate, which equates to adding 25.9 % enzyme (dry matter content) with 74.0 % core particulate component, thus meeting the instant claim limitations. Furthermore, "where appropriate, various additives (adjuncts) may be incorporated together with the enzyme in a granule of the invention. Relevant adjuncts agents may include: metal compounds (e.g. salts and/or complexes of transition metals)," binders and builders (top col. 16). This would, naturally, bring the percentage of the "enzyme or enzyme and granulating agent" component even further above 25%.

Additionally, column 9 discloses the use of other core materials usable to produce the enzyme-containing granules. These include binders and fillers, including salts such as sodium sulphate or sodium chloride, whiteners such as kaolin, etc. Column 8 states that the cores may comprise one or more of binders, fillers, plasticizers and/or fibrous materials. Fillers include salts, clays, talc and silicates.

Also, "one, two or more coating layers may be applied to the dried or partly dried, enzyme-containing granules by conventional methods, such as by pan-coating, mixer-coating, and/or fluid-bed coating.

Finally, as stated at column 4,

Cores forming the basis of enzyme-containing granules of the invention, and cores employed in the process according to the invention, are preferably shaped so that the ratio between the largest and the smallest diameter thereof is less than 3; granules of the invention--whether uncoated or coated (vide infra)--are likewise preferably shaped so that the ratio between the largest and the smallest diameter thereof is less than 3. For both cores and enzyme-containing granules, the latter ratio is preferably less than 2, more preferably less than or equal to 1.5 (i.e. between 1 and 1.5), and it is particularly preferred that the ratio in question is at most 1.2.

Further to this point, Column 10 states that "the overall particle size distribution is preferably relatively narrow, e.g. such that for at least 90%, more preferably 95%, of the particles in a given sample the ratio between the largest and the smallest particle size is less than 4:1, preferably less than 3:1, more preferably less than 2:1, and most preferably less than 1.5:1." This addresses the concept of SPAN difference between the granules, and meets the limitations of instant claims 33-36.

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Thus, the claimed invention is anticipated by the reference.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Keith Hendricks whose telephone number is (571) 272-1401. The examiner can normally be reached on M-F (8:30am-6pm); First Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Milton Cano can be reached on (571) 272-1398. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



**KEITH HENDRICKS
PRIMARY EXAMINER**